



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Helena Laboratories
c/o Ms Patricia Franks
1530 Lindbergh Dr.
P.O. Box 752
Beaumont, TX 77704

JUL 11 2005

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: k050053

Trade/Device Name: HemoRam/AggRAM Analyzer System
Regulation Number: 21 CFR 864.5425
Regulation Name: System, multipurpose in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: January 6, 2005
Received: January 26, 2005

Dear Ms. Franks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

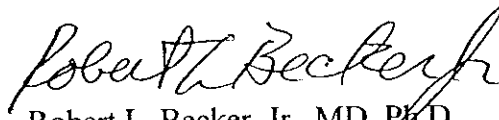
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in cursive script, reading "Robert L. Becker, Jr.", written in dark ink.

Robert L. Becker, Jr., MD, Ph.D

Director

Division of Immunology and Hematology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K050053

Device Name: AggRAM Analyzer

Indications for Use:

The AggRAM Analyzer is a 4-channel aggregometer designed to perform platelet aggregation and Ristocetin cofactor testing on patients for hemostasis abnormalities. Platelet aggregation studies are performed to quantitate platelet response and identify abnormal platelet function. The agonist, Ristocetin, can be used in the diagnosis of von Willebrand's disease. Ristocetin Cofactor reagents are used to quantitate the von Willebrand factor activity.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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510(k) K050053